ulti med Products (Deutschland) GmbH, Reeshoop 1, 22926 Ahrensburg

Ahrensburg, February 2024

Drug tests under IVDR – CE or no CE?

Dear customers,

Due to the upcoming changes in connection with the European IVD Regulation (IVDR) and the associated costs, we as a company have considered what impact this will have on our customers. The considerably more complex certification associated with the IVDR would also increase our costs and therefore the prices of our products.

We would therefore like to explain the differences between CE and non-CE products and how this could affect you:

- The CE mark is an often misinterpreted quality feature. With the CE mark, manufacturers express that their product meets the requirements of a European directive or an EU regulation.

- The CE mark should not be confused with a mark such as the GS mark or the DGUV test mark. In the case of drug tests, for example, the CE marking says nothing about whether a test has been tested by an independent testing and certification body!
  Source: https://www.dguv.de/dguv-test/prod-pruef-zert/ce-konform/index.jsp#:~:text=The%20CE%2Dmarking%20should%20not%20be%20the%20CE%2Dmarking%20not%20from.)

ulti med has been certified to the prestigious DIN EN ISO 13485 quality standard for more than 20 years. This is proof of our successful efforts to carry out all procedures and processes, from development to delivery of our products, with consistently high quality. It should be noted that this quality monitoring also covers all the products we manufacture that do not bear the CE mark.

It is also important to know that the CE marking does not allow any direct conclusions to be drawn about the performance characteristics of a test, but merely proves that the product file of a test fulfills the requirements of the European IVD Regulation. An identical test without CE marking has exactly the same performance characteristics and is of identical quality.

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Please see our Standard Sales and Business Terms on: www.ultimed.org

Important note on distribution:

- CE-marked in-vitro diagnostics are intended exclusively for medical use.
- Non-CE marked products may be sold to any end customer. This could expand your customer base.

We ask you to check in your company whether it is really necessary to purchase a CE product from us in the future.
Enclosed you will find a comparison.

We will of course be happy to answer any questions you may have and discuss this further.

Only if we know what our customers need can we respond to them in the best possible way!

Yours sincerely,

ulti med Products (Deutschland) GmbH

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